P990017

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 28 1999

Mr. Tim R. Williams
Senior Manager of Regulatory Affairs
Guidant Corporation
Cardiac & Vascular Surgery Group
1360 O'Brien Drive
Menlo Park, CA 94025

Re: P990017
ANCURE™ Tube System, ANCURE™ Bifurcated System, ANCURE™ Iliac Balloon Catheter
Filed: March 15, 1999
Amended: March 30, April 1, 5, and 16, May 7 and 24, June 2, 3, 9, and 17, July 12 and 14, 1999

Dear Mr. Williams:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the ANCURE Tube and Bifurcated Systems (models and sizes listed in the enclosure) and the ANCURE Iliac Balloon Catheter (9 mm to 14 mm sizes). This device has the following indications for use:

> The ANCURE™ Tube System is indicated for the endovascular treatment of infrarenal abdominal aortic aneurysms (AAA) in patients having adequate iliac/femoral access, infrarenal non-aneurysmal neck length of at least 15 mm and a diameter of no greater than 26 mm, distal segment neck length of 12 mm and diameter of no greater than 26 mm, and morphology suitable for endovascular repair.
>
> The ANCURE™ Bifurcated System is indicated for the endovascular treatment of infrarenal abdominal aortic or aorto-iliac aneurysms in patients having adequate iliac/femoral access, infrarenal non-aneurysmal neck length of at least 15 mm and a diameter of no greater than 26 mm, distal segment lengths of at least 20 mm and diameters no greater than 13.4 mm, and morphology suitable for endovascular repair.
>
> The ANCURE™ Iliac Balloon Catheter is indicated for use in securing the attachment systems in the iliac arteries and/or

to expand vascular prosthesis limbs of the ANCURE™ ENDOGRAFT® Vascular Prosthesis.

We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify that use of this device is restricted to physicians trained in vascular interventional techniques and in the use of this device, and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

In addition to the postapproval requirements in the enclosure, the following are conditions of this approval:

1. Perform a long-term follow-up study. The goals of this follow-up study are to evaluate the long-term safety and efficacy of the tube and bifurcated Ancure systems and to compare the results to the control patients through five years of implantation. This study is expedited to include all surviving study patients from the original PMA cohort through five years from the date of implantation. All data will be monitored, entered into a database, analyzed and submitted in annual reports to the FDA and a final report will be submitted after completion of the follow-up and analysis. Patients will be followed under the clinical protocols approved under IDE G910177and IDE G940077. At each annual visit a contrast enhanced CT, ultrasound, x-ray and physical examination will be conducted. Clinical data will be recorded on the corresponding case report forms (CRFs) that were used during the EGS and Ancure clinical trials. Data will be collected on all CRF variables. Diagnostic films on patients in this cohort will continue to be evaluated by the Cleveland Clinic Core Laboratory. This follow-up proposal will allow an evaluation of adverse events, implant efficacy, incidence of perigraft flow, aneurysm enlargement and aneurysm rupture over time.

2

2. FDA requests that you implement your training program, as outlined in Amendment 11 and in your letter dated August 21, 1999, in which you state your intention to provide case support for each case performed in the United States. In addition, we request that you continue to evaluate the adequacy of your training program and report on this evaluation annually. Your annual reports should also describe and justify any modifications to your training program.

Expiration dating for this device has been established and approved at six months.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. As part of our reengineering effort, the Office of Device Evaluation is piloting a new process for review of final printed labeling. The labeling will not routinely be reviewed by FDA staff when PMA applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment. Please see the CDRH Pilot for Review of Final Printed Labeling document at http://www.fda.gov/cdrh/pmat/pilotpmat.html for further details.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Megan Moynahan at (301) 443-8517 extension 171.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures
Approved model numbers and sizes
Conditions of Approval

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 7 2001

Mr. Alan Marquardt
Vice President of Regulatory and Clinical Affairs
Guidant Corporation
Cardiac & Vascular Surgery Group
1360 O'Brien Drive
Menlo Park, CA 94025

Re: P990017
ANCURE™ Tube System, ANCURE™ Bifurcated System, ANCURE™ Iliac Balloon Catheter
Filed: March 15, 1999
Amended: March 30, April 1, 5, and 16, May 7 and 24, June 2, 3, 9, and 17, July 12 and 14, 1999.

Dear Mr. Marquardt:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) completed its evaluation of your premarket approval application (PMA), which requested approval for the ANCURE™ Tube System and ANCURE™ Bifurcated System. We notified you that the application was approved in an approval order dated, September 28, 1999. The order listed the ANCURE™ Iliac Balloon Catheter (IBC) as part of the approval.

We now believe we erred in approving this device as part of the PMA. It should have been cleared as a class II device under 21 CFR 870.1240. Any future modifications to the device will require review under 21 CFR 807 Subpart E. Therefore, this letter serves as a correction to your September 28, 1999 approval order by removing the ANCURE™ Iliac Balloon Catheter from the list of devices covered by the order.

If you have any questions about this corrective action, please contact Dorothy Abel at (301) 443-8262, extension 165.

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Table 1. ANCURE™ Tube System Model Numbers

DESCRIPTION	PART NUMBER	MODEL NUMBER	SIZE
TUBE	0305	2009	20x9
TUBE	0305	2010	20x10
TUBE	0305	2011	20x11
TUBE	0305	2012	20x12
TUBE	0305	2013	20x13
TUBE	0305	2014	20x14
TUBE	0305	2015	20x15
TUBE	0305	2016	20x16
TUBE	0305	2209	22x9
TUBE	0305	2210	22x10
TUBE	0305	2211	22x11
TUBE	0305	2212	22x12
TUBE	0305	2213	22x13
TUBE	0305	2214	22x14
TUBE	0305	2215	22x15
TUBE	0305	2216	22x16
TUBE	0305	2409	24x9
TUBE	0305	2410	24x10
TUBE	0305	2411	24x11
TUBE	0305	2412	24x12
TUBE	0305	2413	24x13
TUBE	0305	2414	24x14
TUBE	0305	2415	24x15
TUBE	0305	2416	24x16
TUBE	0305	2609	26x9
TUBE	0305	2610	26x10
TUBE	0305	2611	26x11
TUBE	0305	2612	26x12
TUBE	0305	2613	26x13
TUBE	0305	2614	26x14
TUBE	0305	2615	26x15
TUBE	0305	2616	26x16

Table 2. ANCURE™ Bifurcated System Model Numbers

DESCRIPTION	PART NUMBER	MODEL NUMBER	SIZE
BIFURCATED	0204	201210	20x12
BIFURCATED	0204	201310	20x13
BIFURCATED	0204	201410	20x14
BIFURCATED	0204	201510	20x15
BIFURCATED	0204	201610	20x16
BIFURCATED	0204	201710	20x17
BIFURCATED	0204	201810	20x18
BIFURCATED	0204	201910	20x19
BIFURCATED	0204	221211	22x12
BIFURCATED	0204	221311	22x13
BIFURCATED	0204	221411	22x14
BIFURCATED	0204	221511	22x15
BIFURCATED	0204	221611	22x16
BIFURCATED	0204	221711	22x17
BIFURCATED	0204	221811	22x18
BIFURCATED	0204	221911	22x19
BIFURCATED	0204	241212	24x12
BIFURCATED	0204	241312	24x13
BIFURCATED	0204	241412	24x14
BIFURCATED	0204	241512	24x15
BIFURCATED	0204	241612	24x16
BIFURCATED	0204	241712	24x17
BIFURCATED	0204	241812	24x18
BIFURCATED	0204	241912	24x19
BIFURCATED	0204	261213	26x12
BIFURCATED	0204	261313	26x13
BIFURCATED	0204	261413	26x14
BIFURCATED	0204	261513	26x15
BIFURCATED	0204	261613	26x16
BIFURCATED	0204	261713	26x17
BIFURCATED	0204	261813	26x18
BIFURCATED	0204	261913	26x19

Issued: 3-4-98

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mix-up of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

8

(b)has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3)Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

(1)May have caused or contributed to a death or serious injury; or

(2)Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc.

Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336)and FDA publications entitled "An Overview of the Medical Device Reporting Regulation" (FOD # 509) and "Medical Device Reporting for Manufacturers" (FOD #987) are available on the CDRH WWW Home Page. They are also available through CDRH's Fact-On-Demand (F-O-D) at 800-899-0381. Written requests for information can be made by sending a facsimile to CDRH's Division of Small Manufacturers Assistance (DSMA) at 301-443-8818.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Medical Device Tracking Order

September 28, 1999

Mr. Tim R. Williams
Senior Manager of Regulatory Affairs
Guidant Corporation
Cardiac & Vascular Surgery Group
1360 O'Brien Drive
Menlo Park, CA 94025

RE: abdominal aortic aneurysm stent graft systems

Dear Mr. Williams:

You are notified by this letter of your obligation to adopt a method of tracking for the devices referenced above, as authorized by section 519(e) of the Federal Food, Drug, and Cosmetic Act, (the Act) as amended by section 211 of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The implementation of section 519(e) of the Act, as amended, requires the Food and Drug Administration (FDA) to issue an order to manufacturers when FDA determines that a person who manufactures and distributes a device meets the relevant statutory requirements and tracking is required to protect the public health. This order is effective immediately.

Section 519(e) of the Act, as amended, states that FDA, "...may by order require a manufacturer to adopt a method of tracking a class II or class III device—

(A) the failure of which would be reasonably likely to have serious adverse health consequences; or

(B) which is—

(i) intended to be implanted in the human body for more than one year, or

(ii) a life sustaining or life supporting device used outside a device user facility."

As you know, the corresponding medical device tracking regulations, found in Title 21 Code of Federal Regulations (CFR) Part 821, are intended to ensure that tracked devices can be traced from the device manufacturing facility to the person by whom the device is intended to be used when patient notification (under section 518(a) of the act) or device recall (under section 518(e) of the act) actions are ordered by the agency. The device tracking requirements for exemptions and variances, system and content requirements of tracking, the obligations of persons other than device manufacturers, such as distributors, records and inspection requirements, confidentiality, and record retention requirements, which were published in the **Federal Register** on August 16, 1993, remain in effect. (21 CFR sections 821.2, 821.25, 821.30, 821.50, 821.55 and 821.60, copy enclosed.)

This order to adopt a tracking method does not change your obligations concerning other existing FDA regulations affecting your device. FDA may publish in the **Federal Register** further announcements concerning your device or the medical device tracking requirements under 21 CFR Part 821. Please contact Chet Reynolds in the Office of Compliance at (301) 594-4618 if you need specific guidance. Other general information on your responsibilities under the Act, or more specific information, such as non-binding guidance on medical device tracking, may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http//www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure

12

Federal Register

Monday
August 16, 1993

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 821

Medical Devices; Device Tracking; Final Rules and Request for Comments